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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/564,339 | 01/11/2006 | Ute Isele | H-33301A | 9019 |

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| EXAMINER | |
|---|---|
| HOLT, ANDRIAE M | |
| ART UNIT | PAPER NUMBER |
| 1616 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/564,339 | ISELE, UTE | |
| | Examiner | Art Unit | |
| | Andriae M. Holt | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-35 and 37-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35 and 37-63* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-35 and 37-63 are pending in the application.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I, claim(s) 1-29**, **33-35 and 37-63**, drawn to a highly palatable ductile chewable veterinary composition comprising a) an effective amount of one or more ingredients that are active against animal pests, pathogens or animal diseased, b) meat flavoring, c) partially gelatinized starch, d) a softener, and e) up to 9% water and a method of controlling nonhuman animal pests or nonhuman animal pathogens.

**Group II, claim(s) 30-32**, drawn to method for the production of a highly palatable ductile chewable veterinary composition.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Palatable veterinary compositions containing medicaments and pharmaceuticals with a meat flavoring or masking ingredient are known in the art as evidenced by EP 1,247,456, GB 2,300,103, and US 4,283,400. Thus, a feature found in the prior art cannot be considered to be a special technical feature.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

**Claim 2** recites the following species of "animal diseases":
Viral infections, bacterial infections, behavioral disorders, inflammatory diseases, and auto-immune diseases

**Claim 10** recites the following species of "animal pests":
External animal parasites, international animal parasites

**Claims 15 and 49** recite the following species of "parasiticide":
Eco-parasiticide, endoparasiticide, endecotocide, combination of an eco-parasiticide and an endo-parasiticide, a combination of an eco-parasiticide and endectocide……a combination of an eco-parasiticide, an endo-parasiticide and an endectocide.

**Claims 18 and 52** recite the following species of "parasiticide":
Macrocyclic lactones, benzimidazoles, pro-benzimidazoles…and piperazines.

**Claims 19 and 53** recite the following species of "natural or chemically modified macrocyclic lactone of formula (I)":
$R^1$, $R^2$, X, and Y.

**Claims 22 and 56** recite the following species of "macrocyclic lactone":
Ivermectin, Doramectin…….Nemadectin

**Claims 23 and 57** recite the following species of "anthelmintic":
Albendazole, Clorsulon, Cydectin,……..Thiabendazole

**Claims 28 and 62** recite the following species of "antimicrobial":
Penicillin, tetracycline, sulfonamide,…….and a compound a compound that is active against protozoa

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is required to elect a single species for animal diseases, animal pests, parasiticide, natural

or chemically modified macrocyclic lactone of formula (I), macrocyclic lactone, anthelmintic, and antimicrobial. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

**Claim 2** recites various species of “animal diseases” used in the invention of Group I.

**Claim 10** recites various species of “animal pests” used in the invention of Group I.

**Claim 15 and 49** recite various species of " parasiticide" used in the invention of Group I.

**Claim 18 and 52** recite various species of "parasiticide" used in the invention of Group I.

**Claim 19 and 53** recite various species of " natural or chemically modified macrocyclic lactone of formula (I)" used in the invention of Groups I.

**Claim 22 and 56** recite various species of “macrocyclic lactone " used in the invention of Groups I.

**Claim 23 and 57** recite various species of “anthelmintic" used in the invention of Groups I.

**Claim 28 and 62** recite various species of “antimicrobial" used in the invention of Groups I.

The following claim(s) are generic: 1 and 33

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1 (f)(l)(B)(2), the species are not art recognized equivalents.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

No telephone communication was made because the requirement for restriction is complex.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded in order for the restriction requirement to be complete an election of a single invention from Groups I-II should be made and an election of a single species from the following species: animal diseases, such as behavioral disorders; animal pests, such as external animal parasites; parasiticide, such as eco-parasiticide and macrocyclic lactones; natural or chemically modified macrocyclic lactone of formula (I)-single substituents for $R^1$, $R^2$, X, and Y; macrocyclic lactone, such as ivermectin; anthelmintic, such as albendazole, and antimicrobial such as penicillin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Johann R. Richter/
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